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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,335	12/03/2003	David J. Hammond	2308/660	5513
26774 7590 12/30/2009 NIXON PEABODY LLP - PATENT GROUP 1100 CLINTON SQUARE ROCHESTER, NY 14604				
EXAMINER				
BOESEN, AGNIESZKA				
ART UNIT		PAPER NUMBER		
1648				
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12/30/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/727,335

Applicant(s)

HAMMOND ET AL.

Examiner

AGNIESZKA BOESEN

Art Unit

1648

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 13, 14, 20-37, 40-44, 46 and 47 is/are pending in the application.
- 4a) Of the above claim(s) 20-35, 40-41 and 43-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 13, 14, 36, 37 and 42 is/are rejected.
- 7) ☒ Claim(s) 46 and 47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-944)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/10/2009
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The Amendment filed September 10, 2009 in response to the Office Action March 30, 2009 is acknowledged and has been entered.

Claims 4 and 45 have been canceled. Rejections of canceled claims are moot. New claims 46-47 have been added. Claims 1, 3, 13, 14, 36, 37, 42 and 45-47 are under examination in this Office action.

Information Disclosure Statement

The Information Disclosure Statement received September 10, 2009 has been considered. These documents have been initiated, signed and attached to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of Claims 1, 3 and 4 under 35 U.S.C. 102(b) as being anticipated by Venter et al. (WO 2001/1042-A2) as evidenced by Chesebro et al. (US Patent 6,355,610 B2) is **maintained**.

Applicant's arguments have been fully considered but fail to persuade. Applicant argues that there is no basis for concluding that the Venter sequence would inherently bind to the prior peptide having the amino acid sequence of SEQ ID NO: 1 of the present application and that the PTO's position is insufficient to meet the standard for inherency. Applicant argues that the PTO's argument is devoid of any evidentiary support. Applicant argues that Venter does not

suggest that the disclosed sequence (SEQ ID NO: 20151) binds to the prion peptide having the amino acid sequence of SEQ ID NO: 1 of the present application and that Venter's sequence would not bind to the present SEQ ID NO: 1 because the conformation of the lengthy Venter sequence could mean that the relevant seven amino acid sequence could be buried within the molecule and not exposed for interaction with the prion peptide.

In response to Applicant's arguments the Examiner notes that the sequence disclosed by Venter meets all structural limitations of the claimed SEQ ID NO: 5 because Venter's sequence comprises present SEQ ID NO: 5 and the present claims recite an open claim language with regard to the sequence. The recitation "having an amino acid sequence" is construed as comprising an amino acid sequence. The recitation of "wherein the ligand is capable of binding to a peptide having the amino acid sequence RYPGQ (SEQ ID NO: 1) is viewed as intended use and is therefore not limiting. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on (*In re Schreiber*, 128 F.3d 1473, 1431, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997)).

Because the presently claimed products and the products of the prior art are the same, the products are anticipated/obvious over the cited art. Composition claims that recite a property of the composition are inherently anticipated by the prior art disclosure of that composition; there is

no requirement that the prior art appreciate or recognize the later-discovered property. In contrast, claims to new uses of known processes or compositions are not inherently anticipated by prior art disclosure of the composition or process. The distinction is important in certain areas, such as pharmaceuticals, where claims for new uses of existing compositions routinely issue. The mere recitation of newly-discovered function or property, inherently possessed by things in the prior art, does not cause the claim drawn to those things to distinguish over the prior art (See *In re Best, Bolton, and Shaw* 195 USPQ 430 (CCPA 1977)).

In the present case, the sequence in the prior art meets all structural limitations of the claimed sequence while the functional limitation does not add any further substance to the claimed sequence. Applicant's argument that: Venter sequence would not bind to the present SEQ ID NO: 1 because the conformation of the lengthy Venter sequence could mean that the relevant seven amino acid sequence could be buried within the molecule and not exposed for interaction with the prion peptide, is not found persuasive. Applicant does not know for sure whether the relevant amino acids would be buried within Venter sequence or whether they would be exposed on the surface of the protein. Without any evidence to support Applicant's guess with regard to the sequence disclosed by Verner, it is the position of the Office that Verner's sequence necessarily possesses the claimed characteristics.

Because Verner's sequence meets all the structural limitation of the claimed SEQ ID NO: 5, Verner anticipate the claims and therefore the rejection is maintained.

Rejection of Claims 13 and 14 under 35 U.S.C. 102(b) as being anticipated by Hill (US Patent 5,525,492) **is maintained.**

Applicant's arguments have been fully considered but fail to persuade. Applicant argues there is no basis whatsoever for concluding that the Hill sequence would inherently bind to the native form of the prion protein and that this position is insufficient to meet the standard for inherency. Applicants argue that nowhere does Hill suggest that the disclosed sequence would bind to the native form of the prior protein and that the Hill's SEQ ID NO: 14 is disclosed only as an amino acid sequence that is encoded by a particularly preferred probe.

In response to Applicant's arguments the Office notes that claim 13 recites an open claim language with regard to the claimed SEQ ID NO: 116. Because Hill discloses a sequence that has six amino acids and comprises present SEQ ID NO: 116 (see SEQ ID NO: 14) Hill anticipates all structural limitations with regard to the claimed sequence comprising SEQ ID NO: 116. The recitation: "wherein the ligand is capable of binding to a native form of prion protein (PrPc)" is viewed as intended use and is therefore not considered limiting. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on (*In re Schreiber*, 128 F.3d 1473, 1431, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997)).

Because the presently claimed products and the products of the prior art are the same, the products are anticipated/obvious over the cited art. Composition claims that recite a property of the composition are inherently anticipated by the prior art disclosure of that composition; there is

no requirement that the prior art appreciate or recognize the later-discovered property. In contrast, claims to new uses of known processes or compositions are not inherently anticipated by prior art disclosure of the composition or process. The distinction is important in certain areas, such as pharmaceuticals, where claims for new uses of existing compositions routinely issue. The mere recitation of newly-discovered function or property, inherently possessed by things in the prior art, does not cause the claim drawn to those things to distinguish over the prior art (See *In re Best, Bolton, and Shaw* 195 USPQ 430 (CCPA 1977)).

In the present case, the sequence in the prior art meets all structural limitations of the claimed sequence while the functional limitation does not add any further substance to the claimed sequence. Because Hill discloses a sequence comprising present SEQ ID NO: 116, Hill anticipates the present claims and therefore the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of Claim 36, 37 and 45 under 35 U.S.C. 103(a) as being unpatentable over Venter et al. (WO 2001/1042-A2) as applied to claim 1 and in view of Prusiner et al.. (US Patent 5,750) **is maintained.**

Applicant's arguments have been fully considered but fail to persuade for the reasons discussed above.

Rejection of Claim 42 under 35 U.S.C. 103(a) as being unpatentable over Hill (US Patent 5,525,492) as applied to claim 13 and in view of Prusiner et al. (US Patent 5,750, 361) **is maintained.**

Applicant's arguments have been fully considered but fail to persuade for the reasons discussed above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Rejection of Claims 1, 3, 4, 13, 14, 42 and 45 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 13-19, 36-41, 44 and 47-58 of copending Application No. 12/035,917 **is maintained.** Applicants request that a requirement for terminal disclaimer be held in abeyance until the claims in one of the applications are allowed.

Claim Objections

Claims 46 and 47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claim is allowed. SEQ ID NO: 5 and SEQ ID NO: 116 as closed sequences are free of prior art. Additional sequences SEQ ID NO: 6-13 will be searched once the generic claim is indicated allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on Monday through Friday 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Agnieszka Boesen/
Examiner, Art Unit 1648
/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643